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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,857	03/08/2002	Takashige Nishikawa	JG-YY-5131	2600

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EXAMINER	
MACFARLANE, STACEY NEE	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
02/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/070,857	NISHIKAWA ET AL.	
	Examiner	Art Unit	
	STACEY MACFARLANE	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on September 9, 1999. It is noted, however, that applicant has not filed a certified copy of the 11/255159 application as required by 35 U.S.C. 119(b).

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

It does not identify the citizenship of each inventor.

The instant Oath filed March 8, 2002 is lacking both a mailing address and identification of citizenship and signature for named inventor YANAGAWA, YASUO. Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth.

Sequence compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence identification has been provided for the amino acid sequence "pGlu-Asn-Ser-Pro-Arg-Gly-NH_2" used throughout the instant specification. The claims have been amended to identify this sequence as "SEQ ID NO: 1", but the instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the claims and specification wherever a reference is made to that sequence. See M.P.E.P. § 2422.04.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The claims are indefinite in that they are drawn to an agent capable of treating "nerval diseases" and "glutamate toxicity", which, according to the specification at page 1, encompasses dementia disorders such as Alzheimer's, and mental disorders such as depression, yet the claims explicitly exclude "an antidementia agent" or "an antidepressant agent". Thus, one of ordinary skill in the art would not be reasonably

apprised as to what the metes and bounds of "an agent for treating nerval diseases" include or exclude.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an agent containing SEQ ID NO: 1 for the treatment of dementia, does not reasonably provide enablement for the agent for the treatment of *any* "nerval disease", nor for a specific inhibitor of *any* form of glutamate toxicity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

5. The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

6. With respect to claim breadth, the standard under 35 U.S.C. §112, first paragraph, entails the determination of what the claims recite and what the claims mean as a whole. In addition, when analyzing the scope of enablement, the claims are

analyzed with respect to the teachings of the specification and are to be "given their broadest reasonable interpretation consistent with the specification." See MPEP 2111 [R-5]; *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005); and *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550- 51 (CCPA 1969).

7. As such, the broadest reasonable interpretation agent of the invention containing the active ingredient of SEQ ID NO: 1 is that it allows for the treatment of a vast array of “nerval diseases” and provides specific inhibition for any form of glutamate toxicity. A skilled artisan would not know how to use this agent to treat the broad array of encompassed diseases based solely on the guidance within the instant specification.

8. Although there is no explicit definition within the disclosure for the “nerval diseases” of the claims, the specification teaches that the term encompasses a vast array of diseases associated with abnormal excitatory neurotransmission including, but not limited to, “acute nerval diseases such as paroxysm, brain ischemia, spinal damage, injury of head, ante-partum or postpartum anoxia, brain defect after heart bypass operation or heart transplantation, cardiac standstill, and hypoglycemia”, as well as “chronic nerval diseases such as Alzheimer's disease, Huntington's Chorea, amyotrophy, scleroma of lateral funiculus of spinal, dementia following AIDS, injury of eyes, retinopathy, agnosia, and Parkinson's disease …muscle spasm, convulsion,

migraine, incontinence of urine, breakaway from nicotine, mental diseases such as schizophrenia, epilepsy, brain edema, chronic ache, and tardive dyskinesia" (Specification, page 1). Thus, the claims encompass a broad spectrum of diseases or disorders, each having distinct etiology, pathology, symptoms and patient populations. Even within the current state of the art, for many of these disorders there is no clear nexus between pathology and glutamate toxicity.

9. As opposed to the claims, what is disclosed about the claimed method is narrow: The sole working example (Specification, pages 5-6) is an *in vitro* model comprising inhibition of glutamate toxicity in cultured neurons upon contact with SEQ ID NO: 1. The remaining examples provide direction only for how an injection solution can be made and freeze-dried (Examples 2 and 3, page 7), and guidance that a subcutaneous administration of SEQ ID NO: 1 is non-toxic to rats (Example 4, page 7).

10. In order to practice the invention to the full scope of what is claimed, a skilled artisan would have to make a substantial inventive contribution. The standard of an enabling disclosure is not the ability to make and test if the invention works but one of the ability to make and use with a reasonable expectation of success. In *Genentech, Inc, v. Novo Nordisk*, 42 USPQ 2d 1001, (CAFC 1997), the court held that a patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. The instant specification is not enabling because one cannot follow the guidance presented therein, or the knowledge that was known in the art at the time of filing, to use the agent of the invention as a treatment for *any* nerval disease or as an inhibitor of *any* form of glutamate toxicity,

without further experimentation into the specific mechanisms of the agent, its role in disease or toxicity from various etiological origins, and the means and modes of administration that are effective for successful treatment/inhibition. Therefore, Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, for failing to enablement the invention commensurate in scope with what is claimed.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Masaki et al., US Patent 5,112,947 issued May 12, 1992.

13. Claims 1 and 2 are draw to an agent which contains as an active component a peptide having the formula of SEQ ID NO: 1.

14. The Masaki et al. '947 Patent teaches pharmaceutical compositions containing, as the active ingredient, a peptide that is 100% identical to the instantly claimed SEQ ID NO: 1 (see Claim 2 of the Patent and alignment below from SCORE). The Masaki Patent discloses this peptide as having a neuroprotective effect ("nootropic effect" at Column 1, line 9) and as being therapeutic for a variety of diseases encompassed by the instant claims, including Alzheimer's disease, cerebrovascular dementia, Pick's disease, Huntington's disease, vCJD, Parkinson's and cerebellar myelic denatured

disease (paragraph bridging Columns 5-6). Thus, the agent of the instant claims fails to distinguish over that taught by the Masaki et al. prior art Patent, and the claims are rejected as being anticipated.

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AAR07438
ID   AAR07438 standard; protein; 6 AA.
XX
AC   AAR07438;
XX
DT   25-MAR-2003  (revised Patent Assignee)
DT   01-FEB-1991  (first entry)
Masaki M,  Uehara M,  Hirate K,  Isowa Y,  Sato Y,  Nakashima Y;
EP393934-A.
XX
PD   24-OCT-1990.
XX
PF   12-APR-1990;   90EP-00303987.
XX
PR   15-APR-1989;   89JP-00095917.
PR   15-APR-1989;   89JP-00095918.
PR   15-APR-1989;   89JP-00095919.
PR   15-APR-1989;   89JP-00095920.
PR   15-APR-1989;   89JP-00095921.
PR   15-APR-1989;   89JP-00095922.

  Query Match             100.0%;  Score 33;  DB 1;  Length 6;
  Best Local Similarity   100.0%;
  Matches    6;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 ENSPRG 6
              ||||||
Db          1 ENSPRG 6
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Conclusion

15. No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-R 5:45 to 3:30, TELEWORK-Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

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